

Application No. 09/593,591
Amendment dated March 16, 2010

REMARKS

Applicant cancelled dependent claims 284, 287, 290, 293, 296, and 299 without any prejudice or disclaimer of their subject matter and amended independent claims 1, 85, 163, 203, 223, and 263 to further define Applicant's claimed invention. Support for the amendments to independent claims 1, 85, 163, 203, 223, and 263 can be found at least on page 1, lines 3-5, page 9, lines 11-12, and in Fig. 10 of the application. No new matter has been added.

I. Rejection Under 35 U.S.C. § 112, first paragraph and Objection to the Specification

The Examiner rejected claims 1, 2, 4, 5, 7-20, 22-30, 32-42, 85, 86, 88, 89, 91-129, 148-152, 155-164, 166, 168-182, 203, 204, 206, 208-224, 226, 228-242, 263, 264, 266, and 268-300 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement; and objected to the specification as failing to provide proper antecedent basis for the claimed subject matter.

The Examiner objected to the following recitations of independent claims 1, 85, 163, 203, 223, and 263: the "first dimension" and the "second dimension" and their relative lengths; a "plane perpendicular to and bisecting the length of said body into two parts of equal maximum length along the mid-longitudinal axis . . . the plane passing through at least a portion of said opening;" and the trailing end having a "non-linear portion between two lines parallel to the mid-longitudinal axis." Applicant maintains the position that Fig. 10 as originally filed supports the above-quoted recitations of Applicant's claimed invention. Nonetheless, Applicant deleted these recitations from the independent claims in order to expedite the prosecution of this application.

The Examiner further objected to the claim language reciting that opposite exterior sides of the implant have "straight portions that are generally parallel to each other." Per the Examiner's suggestion, Applicant deleted the term "generally" in front of "parallel" in order to expedite the prosecution of this application.

The Examiner further objected to the claim language reciting that the "maximum width [of the opening is] transverse to the mid-longitudinal axis" of the body of the implant. Applicant respectfully disagrees with the Examiner's contention that "a mid-longitudinal axis of Figure 10 would run vertically on the page that Figure 10 is located."

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(Office Action, page 9, lines 17-18). The MPEP sets forth that "[a]n applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning(s). See *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994)." (MPEP § 2111.01 (IV), page 2100-41, col. 1.) Applicant's specification states that "the mid-longitudinal axis of the bone ring implant" is "defined by a line passing through the center of the bone ring implant from its leading end to its trailing end." (Specification, page 3, lines 14-16.) Independent claims 1, 85, 163, 203, 223, and 263 each recite that the body of the implant has "a leading end, a trailing end opposite said leading end and . . . a mid-longitudinal axis passing through said leading and trailing ends." In Fig. 10, the trailing end is the curved portion proximate openings 120, 122, and the leading end is the straight portion opposite the trailing end. Accordingly, the mid-longitudinal axis passing through the leading and trailing ends runs horizontally on the page that Fig. 10 is located, and the maximum width of opening 114 is transverse to the mid-longitudinal axis of the implant.

The MPEP sets forth that "[a]n applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. See, e.g., *Vas-Cath*, 935 F.2d at 1565, 19 USPQ2d at 1118 ('drawings alone may provide a 'written description' of an invention as required by Sec. 112*')." (MPEP, § 2163, page 2100-178, col. 2.) Applicant submits that as required by 35 U.S.C. § 112, first paragraph, at least Fig. 10 of the specification describes the claimed invention in such a way as to reasonably convey to one skilled in the art that Applicant was in possession of the claimed invention.

37 C.F.R. § 1.75(d)(1) sets forth that the "claim or claims must conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description." (Emphasis added.) As discussed above, the term "mid-longitudinal axis" is defined in the specification. Applicant submits that in compliance with 37 C.F.R. §

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1.75(d)(1), FIG. 10, which was part of the original specification, provides clear support to the claim phrase "[said opening having] a maximum width transverse to the mid-longitudinal axis," objected to by the Examiner. Accordingly, Applicant submits that the meaning of the claim terms objected to by the Examiner may be ascertainable by reference to at least FIG. 10 of the specification, and that literal antecedent basis in the description for such claim terms is not required.

Furthermore, Applicant respectfully disagrees with the Examiner's contention that "Figures are not drawn to scale so one cannot utilize them to determine relative dimensions; see MPEP 2125." (Office Action, page 9, line 22 through page 10, line 1.) According to MPEP § 2125, "the description of the article pictured can be relied on, in combination with the drawings, for what they would reasonably teach one of ordinary skill in the art." (MPEP § 2125, page 2100-59, col. 1.) Applicant submits that without requiring one of ordinary skill in the art to measure the drawing features, Fig. 10 reasonably teaches one of ordinary skill in the art that the maximum width of opening 114 is transverse to the mid-longitudinal axis defined in the specification. Accordingly, the claim element "[said opening having] a maximum width transverse to the mid-longitudinal axis," does not violate the principles set forth in MPEP § 2125.

II. Rejections Under 35 U.S.C. § 103(a)

The Examiner rejected claims 1, 2, 4, 5, 7-12, 14, 16, 85, 86, 88, 89, 91-96, 98, 100, 102-105, 116, 117, 163, 164, 166, 168-173, 175, 179-180, 203, 204, 206, 208, 209, 211, 213, 215, 223, 224, 228-229, 231, 233, 235, 239, 240, 263, 264, 266, 268-269, 271, 273, 275, 279, and 280 under 35 U.S. § 103(a) as obvious over WO98/17209 to Pafford et al. ("Pafford") in view of U.S. Patent No. 5,861,041 to Tienboon ("Tienboon") or WO 99/08627 to Gresser et al. ("Gresser") or U.S. Patent No. 5,607,424 to Tropiano ("Tropiano"). Applicant amended independent claims 1, 85, 163, 203, 223, and 263 to recite an interbody spinal implant having a body manufactured from a bone ring and including "an opening formed by the medullary canal" passing through its upper and lower surfaces, the opening "having a perimeter with substantially the same configuration as a perimeter of the natural medullary canal present when the major long bone is cut transverse to the medullary canal to form the bone ring."

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Applicant submits that Figs. 29-32 of Pafford, referred to by the Examiner on page 4, lines 13-16 of the Office Action, show that chamber 130 of the implant does not have "a perimeter with substantially the same configuration as a perimeter of the natural medullary canal present when the major long bone is cut."

Accordingly, the implant in Figs. 29-32 of Pafford does not embody all of the recitations of Applicant's independent claims 1, 85, 163, 203, 223, and 263, as now amended. Furthermore, Applicant submits that none of Tienboon, Gresser, and Tripano teach or suggest an implant including "an opening formed by the medullary canal" passing through its upper and lower surfaces, the opening "having a perimeter with substantially the same configuration as a perimeter of the natural medullary canal present when the major long bone is cut transverse to the medullary canal to form the bone ring." Thus, the proposed combination does not teach or suggest each and every element of independent claims 1, 85, 163, 203, 223, and 263, as now amended.

Applicant submits that the rejection of the claims under 35 U.S. § 103(a) over Pafford in view of Tienboon or Gresser or Tripano has been overcome.

The Examiner rejected claims 1-2, 4, 5, 7-20, 22, 25, 30, 32-35, 85, 86, 88, 89, 91-106, 109, 114-119, 127-129, 148, 158, 163, 164, 171, 174, 175, 179, 180, 203, 204, 206, 208-211, 213-215, 219, 220, 223, 224, 226, 228-231, 233-235, 239, 240, 263, 264, 266, 268-271, 273-275, 279, 280, 285, 288, 291, 294, 297, and 300 under 35 U.S. § 103(a) as being unpatentable over U.S. Patent No. 6,277,149 to Boyle et al. ("Boyle") in view of Tienboon or Gresser or Tripano.

Applicant amended independent claims 1, 85, 163, 203, 223, and 263 to recite that the opening "formed by the medullary canal" has a "maximum length in a direction parallel to the mid-longitudinal axis and a maximum width transverse to the mid-longitudinal axis," the "maximum width being greater than the maximum length." Applicant's Fig. 10 is reproduced and annotated below to show the claimed elements.

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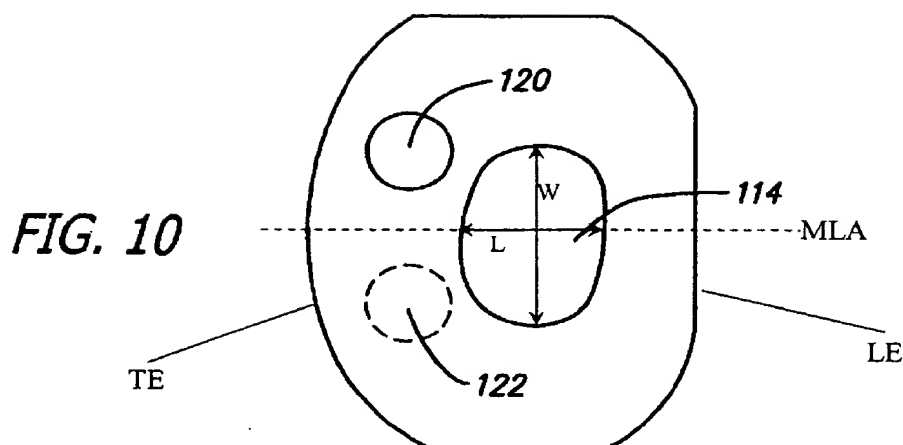


Fig. 10 above shows that the maximum width (W) of opening 114 in a direction transverse to the mid-longitudinal axis (MLA) passing through the leading end (LE) and the trailing end (TE) of the implant is greater than the maximum length (L) of opening 114. Conversely, Figs. 6, 7, 10, 11, 14, 17, and 18 of Boyle show that the opening in the implant is a circle. Thus, the maximum width of the openings in the implants of Boyle is equal to, not greater than, the maximum length of the openings.

Applicant submits that the implant in Boyle does not teach or suggest an implant embodying all of the recitations of Applicant's independent claims 1, 85, 163, 203, 223, and 263, as now amended. Furthermore, Applicant submits that none of Tienboon, Gresser, and Tripiano teach or suggest an implant including "an opening formed by the medullary canal," the "maximum width of said opening being greater than the maximum length." Thus, the proposed combination does not teach or suggest each and every element of independent claims 1, 85, 163, 203, 223, and 263, as now amended.

Applicant submits that the rejection of the claims under 35 U.S. § 103(a) over Boyle in view of Tienboon or Gresser or Tropiano has been overcome.

The Examiner rejected claims 26-29, 110-113, 149-152, 159-162, 172, 177, 178, 182, 212, 217, 218, 222, 232, 237, 238, 242, 272, 277, 278, and 282 under 35 U.S. §103(a) as being unpatentable over Boyle, Tienboon, Gresser, and Tropiano as used in the previous rejection, further in view of U.S. Patent No. 5,397,364 to Kozak et al.

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("Kozak"); rejected claims 36-42, 120-126, 166, 168-170, 173, 181, 206, 221, 241, and 281 under 35 U.S. § 103(a) as being unpatentable over Boyle, Tienboon, Gresser, and Tropiano as applied in the rejection of claim 1 above in further view of the suggestions of Boyle; rejected claims 23, 24, 107, 108, 176, 216, 236, and 276 under 35 U.S. § 103(a) as being unpatentable over Boyle, Tienboon, Gresser, and Tropiano as applied against claim 1 above, further in view of U.S. Patent No. 5,669,909 to Zdeblick ("Zdeblick"); rejected claims 283, 284, 286, 287, 289, 290, 292, 293, 295, 296, 298, and 299 under 35 U.S. § 103(a) as being unpatentable over Boyle in view of Tienboon. Applicant submits that the rejections of claims 23, 24, 26-29, 36-42, 107, 108, 110-113, 120-126, 149-152, 159-162, 166, 168-170, 172, 173, 176-178, 181, 182, 206, 212, 216-218, 221, 222, 232, 236-238, 241, 242, 272, 276-278, 281-284, 286, 287, 289, 290, 292, 293, 295, 296, 298, and 299 are rendered moot at least because these claims depend from an allowable independent claim, or claims dependent therefrom.

Applicant submits that independent claims 1, 85, 163, 203, 223, and 263 are patentable and that dependent claims 2, 4, 5, 7-20, 22-30, 32-42, 86, 88, 89, 91-129, 148-152, 158-162, 164, 166, 168-182, 204, 206, 208-222, 224, 226, 228-242, 264, 266, and 268-300, dependent from one of independent claims 1, 85, 163, 203, 223 and 263, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

Applicant respectfully requests that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing the pending claims in condition for allowance.

Applicant submits that the entry of the amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

In view of the foregoing remarks, Applicant submits that the claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Entry and consideration of this Amendment prior to the further examination of the above-identified application is respectfully requested.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including

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any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-3726.

Respectfully submitted,

MARTIN & FERRARO, LLP

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By: 
Amedeo F. Ferraro
Registration No. 37,129

1557 Lake O'Pines Street, NE
Hartville, Ohio 44632
Telephone: (310) 286-9800
Facsimile: (310) 286-2795